K003497

NOV 3 0 2000

Non-Confidential Summary of Safety and Effectiveness

10-Nov-00

Engineered Medical System, Inc.
2055 Executive Dr.
Indianapolis, IN 46241

Tel - (317) 246-5500
Fax - (317) 246-5501

Official Contact:	Bonnie Holly – Quality Manger
Proprietary or Trade Name:	Disposable manometer
Common/Usual Name:	Pressure manometer
Classification Name:	Airway Pressure monitor
Device:	Disposable manometer
Predicate Devices:	Mercury Medical – Pressure Manometer – K954486
	SIMS Portex – 1st Response Manometer – K961318

Device Description:

The EMS disposable pressure manometer is a means of providing visual indication of patient airway pressure during ventilation. The device consists of: A flexible nipple for attachment to a sampling / pressure port, Clear polycarbonate (PC) housing with a printed pressure scale, PC float with indicator, and a spring.

Intended Use:

Indicated Use --	To provide visual indication of a patient's airway pressure during Ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.
Environment of Use --	Home, Physician office, Outdoor environments, Hospital, Sub-acute Institutions, Emergency services, anywhere airway prssure is measured

Comparison to Predicate Devices:

Attribute	Proposed device	Mercury K954486	SIMS 1st Response K961318
Intended use	To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.	Same	Same

Attribute	Proposed device	Mercury K954486	SIMS 1st Response K961318
Intended for single patient, multi-use	Yes	Yes	Yes
Prescription	No Used by personnel thoroughly trained in the techniques of pulmonary resuscitation or airway management.	No Same	No Same
Intended population	Any patient requiring airway pressure measurement	Same	Same
Intended Environment of Use	Home, Hospital, Physician Office, sub-acute, Emergency services, any where airway measured is desired	Same	Same
Design Features			
Range of pressures measured	0-50 cm H_2O	0-80 cm H_2O	0-50 cm H_2O
Can be used on different ventilation devices	It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.	Yes	Yes
Materials			
Polycarbonate, PC	Yes Material certification provide for other devices	Yes	Yes
Contains latex	No	No	No
Performance	Delivers same oxygen concentration at lower flows		
Accuracy cm H2O over the range	$\pm$ 1 cm H_2O / 0-10 $\pm$ 2 cm H_2O /10-40 $\pm$ 3 cm H_2O / > 40	$\pm$ 3 cm H_2O / 15 $\pm$ 5 cm H_2O / 60	$\pm$ 2 cm H_2O / 0-10 $\pm$ 5 cm H_2O /20-50 $\pm$ 10 cm H_2O / > 50

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2000

Mr. Paul Dryden
Promedic, Inc.
Official Corresponedant for
Engineered Medical Systems
6329 W. Waterview Ct.
McCordsville, IN 46055

Re: K003497
Trade Name: Disposable Pressure Monitor
Regulatory Class: II (two)
Product Code: CAP
Dated: November 10, 2000
Received: November 13, 2000

Dear Mr. Dryden:

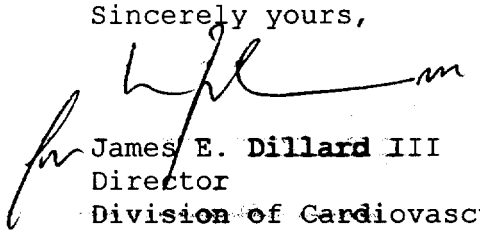
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K003497 (To be assigned)

Device Name: Disposable Manometer

Intended Use: To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003497

Prescription Use ___ **or** **Over-the-counter use** X
(Per CFR 801.109)